PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Hans O. Ribi *et al.*

Serial No.: 09/892,018

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Title: **INGESTIBLES POSSESSING INTRINSIC COLOR CHANGE**

Examiner: Rachel M. Bennett

Art Unit: 1615

MARKED UP VERSION OF CLAIMS

Commissioner for Patents
Washington, D.C. 20231

Sir:

The Examiner is respectfully requested to make the following amendments. A "Clean Version" of the Claims is attached hereto together with replacement pages 54-63.

In the claims

1. (Reiterated) An ingestible comprising a chromic change agent that undergoes a color change one or more times in response to at least one physical or chemical triggering mechanism.

2. (Reiterated) The ingestible according to Claim 1, wherein said physical or chemical triggering mechanism is selected from the group consisting of light, mechanical stress, change in temperature,

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change of pH, change in hydration, change in solvation, change of ionization potential, change of solvents, and change in certain chemical constituents in an ingestible matrix.

3. (Reiterated) The ingestible according to Claim 1, wherein said ingestible comprises a food, a medicament, a toothpaste, a mouthwash, a gargle or a swab.

4. (Reiterated) The ingestible according to Claim 1, in which said chromic change agent is a mono- or polydiacetylenic compound.

5. (Amended) The ingestible according to Claim 4, wherein said a mono- or polydiacetylenic compound [compound] is halogenated to increase a temperature at which said color change occurs.

6. (Reiterated) The ingestible according to Claim 1, wherein said physical or chemical triggering mechanism is a change in a state from the group consisting of temperature, pH, illumination, ionization, protonation, hydrogen bonding, hydration, solvation, exposure to a triggering chemical, exposure to a triggering biochemical, mechanical stress, and a combination of two or more of said physical or chemical triggering mechanisms.

7. (Reiterated) The ingestible according to Claim 6, wherein said physical triggering mechanism is a modification in temperature and said color change is irreversible.

8. (Reiterated) The ingestible according to Claim 6, wherein said illumination comprises visible light or ultraviolet light at a wavelength of about 254 nanometers.

9. (Reiterated) The ingestible according to Claim 6, wherein said triggering chemical comprises alcohol or acetone.

10. (Reiterated) The ingestible according to Claim 6, wherein said wherein said chemical triggering mechanism is enzymatic activity.

11. (Reiterated) The ingestible according to Claim 10, wherein said enzymatic activity is microbial enzymatic activity.

12. (Reiterated) The ingestible according to Claim 6, wherein said color change one or more times in response to at least one physical or chemical triggering mechanism is sequential.

13. (Reiterated) The ingestible according to Claim 6, wherein said mechanical stress comprises friction, pressure, or sheer.

14. (Reiterated) The ingestible according to Claim 13, wherein said friction is rubbing, sheering, striking, compressing or scratching.

15. (Reiterated) An ingestible comprising a diacetylenic compound having a color transition temperature in a range of about -20 to 350°C.

16. (Reiterated) The ingestible according to Claim 15, wherein said color transition temperature is in a range of about -10 to 200°C.

17. (Reiterated) The ingestible according to Claim 16, wherein said ingestible is a solid.

18. (Reiterated) The ingestible according to Claim 16, wherein said ingestible is a liquid.

19. (Reiterated) The ingestible according to Claim 16, wherein said diacetylenic compound is a homopolymer.

20. (Reiterated) The ingestible according to Claim 16, wherein said diacetylenic compound is a copolymer.

21. (Reiterated) A liquid ingestible comprising a diacetylenic compound having a transition temperature in a range of about -10 to 200°C dispersed therein.

22. (Reiterated) A solid ingestible having a coating comprising a diacetylenic compound having a transition temperature in a range of about -10 to 200°C.

23. (Reiterated) The solid ingestible according to Claim 22, wherein said diacetylenic compound interpenetrates said solid ingestible.

24. (Reiterated) A composition comprising a carbohydrate and a diacetylenic compound having a transition temperature in a range of about -10 to 200°C.

25. (Reiterated) A composition comprising a lipid and a diacetylenic compound having a transition temperature in a range of about -10 to 200°C.

26. (Reiterated) An ingestible comprising a diacetylenic compound, wherein said diacetylenic compound comprises an end group selected from the group consisting of a carboxylic acid or derivative thereof, an hydroxy group or ether thereof, and an amino group or derivative thereof.

27. (Reiterated) N-ethanol-hexadeca-5,7-diyneamide, or derivatives thereof.

28. (Reiterated) A diacetylenic compound that undergoes a change color one or more times in response to a change in temperature comprising N-propylamine-eicosa-5,7-diyneamide, or derivatives thereof.

29. (Reiterated) A solid ingestible comprising a diacetylenic compound having a transition temperature in a range of about -10 to 200°C and at least one food dye, wherein a combination of said polymer and said at least one food dye imparts to said solid ingestible a color of said at least one food dye different from a color of said polymer in one of its transitions.

30. (Reiterated) A sugar icing comprising a diacetylenic compound having a transition temperature in a range of about -10 to 200°C.

31. (Reiterated) A lipid ingestible coating composition comprising a diacetylenic compound having a transition temperature in a range of about -10 to 200°C.

32. (Amended) <u>The ingestible according to Claim 1</u> [An ingestible having], <u>wherein said chromic change agent comprises</u> an interpenetrating coating of a diacetylenic compound [having], <u>said</u>

[redacted]

physical triggering mechanims is a transition temperature in a range of about -10 to 200°C, and wherein said ingestible is selected from the group consisting of medicaments, meats, confections, candy, baby food, cereals, marshmallows, cheese, hot and cold beverages, and baked goods.

33. (Reiterated) A liquid ingestible having dispersed therein a diacetylenic compound having a transition temperature in a range of about -10 to 200°C wherein said ingestible is selected from the group consisting of hot and cold beverages, formulas and syrups.

34. (Amended) The ingestible according to Claim 1, wherein said ingestible is a [A] solid food having an adherent coating comprising a design formed by said chromic change agent, wherein said chromic change agent is a polydiacetylenic polymer [that undergoes a color transition in response to] and said physical mechanism is a modification of temperature.

35. (Reiterated) The solid food according to Claim 34, wherein said adherent coating comprises rice paper.

36. (Reiterated) A solid material in contact with food comprising a diacetylenic compound having a transition temperature in a range of about -10 to 200°C.

37. (Reiterated) The solid material according to Claim 36, wherein said solid material is a packaging material or food container.

38. (Reiterated) An ingestible comprising a diacetylenic compound that indicates freshness or safe status of a food item.

39. (Reiterated) The ingestible according to Claim 38, wherein a color change by said diacetylenic compound indicates maximum achieved cooking temperature, duration of cooking period, duration of storage, or maximum storage temperature.

40. (Reiterated) The ingestible according to Claim 38, wherein a color change by said diacetylenic compound indicates active metabolism occurring within said ingestible.

41. (Reiterated) The ingestible according to Claim 40, wherein said active metabolism is microbial metabolism.

42. (Reiterated) The ingestible according to Claim 41, wherein said microbial metabolism indicates likelihood of a microbial pathogen or food spoilage agent in said ingestible.

43. (Reiterated) An ingestible comprising a diacetylenic compound, wherein said diacetylenic compound comprises as an end group a carboxylic acid or derivative thereof, a hydroxy group or ether thereof, or an amino group or derivative thereof.

44. (Reiterated) A method for effecting at least one color change in or on an ingestible, comprising;

incorporating into or onto said ingestible a diacetylenic compound that undergoes said at least one color change when subjected to at least one environmental change; and

subjecting said ingestible to said at least one environmental change, whereby said at least one environmental change triggers said at least one color change on said ingestible.

45. (Reiterated) The method according to Claim 44, in which said at least one environmental change is selected from the group consisting of change in temperature, pH, illumination, chemical exposure, biochemical exposure, mechanical stress, ionization, protonation, hydrogen bonding, state of hydration, and state of solvation.

46. (Reiterated) The method according to Claim 44, wherein said ingestible comprises a food, medicament or swab.

47. (Reiterated) The method according to Claim 44, wherein said at least one color change forms at least one pattern on said ingestible.

48. (Reiterated) The method according to Claim 47, wherein said at least one pattern is selected from the group consisting of text, characters, images, symbols, branding identities, trademarks, messages, icons, logos, artistic designs and decorative designs.

49. (Reiterated) The method according to Claim 48, wherein said at least one pattern is changed

sequentially in time-resolved text or images.

50. (Reiterated) A method for effecting one or more color changes on a packaging material or container for holding an ingestible, comprising;

incorporating into or onto said packaging material or container a diacetylenic compound that undergoes a color change when subjected to at least one environmental change selected from the group consisting of change in temperature, pH, illumination, chemical or biochemical exposure, mechanical stresses, ionization, protonation, hydrogen bonding, state of hydration or solvation; and

subjecting said packaging material or container to said at least one environmental change.

51. (Reiterated) A method for detecting whether an ingestible has been exposed to an absolute temperature level, said method comprising:

associating with said ingestible a diacetylenic compound that undergoes an irreversible color change when subjected to a change in temperature, wherein a color change associated with said ingestible is indicative that said ingestible has been exposed to said absolute temperature level.

52. (Reiterated) The method according to Claim 51, wherein said diacetylenic compound is attached to a container or packaging material for ingestibles.

53. (Reiterated) The method according to Claim 51, wherein said color change indicates said ingestible has been spoiled.

54. (Reiterated) The method according to Claim 51, wherein said color change indicates said ingestible is cooked.

55. (Reiterated) A method for indicating a temperature of an ingestible, said method comprising:

incorporating a diacetylenic compound that undergoes a reversible color change when subjected to a change in temperature in or on said ingestible or an ingestible container, whereby color of said diacetylenic compound is indicative of said temperature when said color is observed.

56. (Reiterated) A method for detecting whether an ingestible has been exposed to moisture, said method comprising:

associating with said ingestible a diacetylenic compound that undergoes an irreversible color change when subjected to moisture, wherein a color change associated with said ingestible is indicative that said ingestible has been exposed to said moisture.

57. (Reiterated) A method for detecting whether an ingestible has achieved a safe cooking level and has cooled to a temperature that is safe to eat, said method comprising:

associating with said ingestible a diacetylenic compound that undergoes an irreversible color change when subjected to a safe cooking temperature and a reversible color change when said diacetylenic compound reaches said temperature that is safe to eat, wherein said irreversible color change is indicative that said ingestible has achieved said safe cooking level and said reversible color change is indicative that said ingestible has reached said temperature that is safe to eat.

58. (Reiterated) A method for indicating elevated body temperature in a mammal, comprising:

administering to said mammal an ingestible comprising a diacetylenic compound, wherein said diacetylenic compound undergoes a color change at a temperature above normal body temperature of said mammal; and

observing said ingestible for said color change, wherein said a color change is indicative of an elevated body temperature.

59. (Reiterated) The method according to Claim 58, wherein said ingestible is a lozenge, pill, tablet, probe, mouthwash or gargle.

60. (Reiterated) A method for protecting a food comprising a diacetylene compound from premature color change, said method comprising:

associating with said ingestible a diacetylenic compound that reversibly changes color when subjected to a change in temperature, and irreversibly changes color when subjected to a different environmental change.

61. (Reiterated) The method according to Claim 60, wherein said food is a cereal and said different environmental change is exposure to a liquid.

62. (Reiterated) A method of applying a pattern on a surface of an ingestible, wherein said method

comprises:

applying a diacetylenic compound in varying concentrations to an ingestible or ingestible container, whereby a local level of polymerization of said diacetylenic compound is used to create a changing graphic throughout a temperature triggering process.

63. (Reiterated) A method for manufacturing an ingestible comprising a diacetylenic compound, wherein said method comprises:

applying said diacetylenic compound by ink jet printing, dot matrix printing, offset printing, pad printing, extrusion, spraying, use of liquid applicators, dip coating, sublimation, spreading, dripping, dye sublimation printing, or by application of laminates or edible labels.

64. (Reiterated) A method for manufacturing an ingestible comprising a diacetylenic compound, said method comprising applying said diacetylenic compound in a composition of up to 75% weight % of a diacetylenic compound.

65. (Reiterated) The method according to Claim 64, whereby said composition is up to about 60% weight % of a diacetylenic compound.

66. (Reiterated) The method according to Claim 64, whereby said composition of up to about 20% weight % of a diacetylenic compound.

67. (Reiterated) The method according to Claim 64, wherein said diacetylenic compound is a lipid mono- or dicarboxylic non-oxo carbonyl monomer, or derivative thereof.

68. (Reiterated) A diagnostic device comprising at least one chromic change agent that undergoes at least one color change, wherein said at least one color change records a physiological process.

69. (Reiterated) The diagnostic device according to Claim 68, wherein said at least one color change is irreversible and permanently records a physiological process.

70. (Reiterated) The diagnostic device according to Claim 68, wherein said at least one color change is reversible and repeatedly records a physiological event.

71. (Reiterated) The diagnostic device according to Claim 68, wherein said at least one color change is changed to its original color to determine the conditions in which said at least one color change took place.

72. (Reiterated) The diagnostic device according to Claim 68, wherein said at least one chromic change agent is selected from the group consisting of diacetylenic compounds, leucodyes, transition melting waxes, pigments released during hydration or shear, micro and nano pigments, molybdenum, doped and undoped vanadium dioxide, mercuric iodide, indolinospirochromenes, spiropyrans, polybithiophenes, di-β-napthospiropyrans, and derivatives thereof.

73. (Reiterated) The diagnostic device according to Claim 68, wherein said diagnostic device is retained in the mouth for a length of time sufficient to cause said at least one color change.

74. (Reiterated) The diagnostic device according to Claim 73, wherein said diagnostic device is a chewing gum, mouthwash, gargle, spray or lozenge.

75. (Reiterated) The diagnostic device according to Claim 68, wherein said diagnostic device travels through the digestive tract and said at least one color change occurs in response to conditions said diagnostic device encounters within said digestive tract.

76. (Reiterated) The diagnostic device according to Claim 68, wherein said diagnostic device detects inability to metabolize food components.

77. (Reiterated) The diagnostic device according to Claim 76, wherein said diagnostic device is a mouth wash, gargle, or spray.

78. (Reiterated) A method for written or graphical communication displayed on an ingestible, said method comprising at least two chromic change agents, wherein said chromic change agents display at least two sequentially-ordered directives which appear or disappear as said ingestible is processed according to said directives.

79. (Reiterated) An ingestible comprising one or more chromic change agents selected from the group consisting of leucodyes, transition melting waxes, pigments released during hydration or shear, micro and nano pigments, molybdenum, doped and undoped vanadium dioxide, mercuric iodide, indolinospirochromenes, spiropyrans, polybithiophenes, di-β-napthospiropyrans, and derivatives thereof.

80. (Reiterated) The ingestible according to Claim 79, wherein said one or more chromic change agents change color after exposure to at least one change in the environment of said one or more chromic change agents, wherein said change in the environment is selected from the group consisting of a change in temperature, a change in pH, a change in illumination, a change in chemical exposure, a change in mechanical stress, a change in ionization, a change in protonation, a change in hydrogen bonding, a change in state of hydration, and a change in solvation.

81. (Reiterated) The ingestible according to Claim 79, wherein said one or more chromic change agents are incorporated in or on said ingestible in a pattern selected from the group consisting of text, characters, images, symbols, branding identities, trademarks, messages, icons, logos, artistic designs and decorative designs.

82. (Reiterated) The ingestible according to Claim 79, wherein said one or more chromic change agents change to more than one color in sequential manner when exposed to one or more triggering mechanisms.

83. (Reiterated) The ingestible according to Claim 80, wherein said at least one change in the environment comprises exposure to salivary components including chemicals, biochemicals, pre-digestive effectors or enzymes.

84. (Reiterated) The ingestible according to Claim 83, wherein said one or more chromic change agents are chemically modified with starch or carbohydrate moieties and said enzymes break down starch or carbohydrates.

Respectfully submitted,

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